

## 510(k) SUMMARY

16141647

1. Date: July 15, 2014 **JUL 17 2014**

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4. Device Name: Healgen COC One Step Cocaine Test (Strip, Cassette, Cup, Dip Card)  
Healgen MOP One Step Morphine Test (Strip, Cassette, Cup, Dip Card)

## Classification:

Product Code	CFR #	Panel
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

## 5. Predicate Devices:

K052115

First Check Multi Drug Cup 12

## 6. Intended Use

Healgen COC One Step Cocaine Test is an immunochromatographic assay for the qualitative determination of Benzoylecgonine in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen MOP One Step Morphine Test is an immunochromatographic assay for the qualitative determination of morphine in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

## 7. Device Description

Healgen COC One Step Cocaine Test and Healgen MOP One Step Morphine Test are immunochromatographic assays for Cocaine and Morphine. Each assay test is a lateral flow, one step system for the qualitative detection of Benzoylecgonine and Morphine (target analyte) in human urine. The product is a single-use in vitro diagnostic device, which comes in the form of: Strips, Cassettes, DipCards, or Cups. It contains a Test Device (in one of the four formats), a package insert and a urine cup. Each test device is sealed with a desiccant in an aluminum pouch.

## 8. Substantial Equivalence Information

A summary comparison of features of the One Step Cocaine Test and One Step Morphine Test and the predicate device is provided in Table 1 & Table 2.

**Table 1: Features Comparison of Healgen COC One Step Cocaine Test and the Predicate Device**

Item	Device	Predicate - K052115
Indication(s) for Use	For the qualitative determination of Benzoylecgonine in human urine.	Same
Calibrator	Benzoylecgonine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

**Table 2: Features Comparison of Healgen MOP One Step Morphine Test and the Predicate Device**

Item	Device	Predicate - K052115
<b>Indication(s) for Use</b>	For the qualitative determination of Morphine in human urine.	Same
<b>Calibrator</b>	Morphine	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Specimen Type</b>	Human Urine	Same
<b>Cut-Off Values</b>	300 ng/mL	Same
<b>Intended Population</b>	For over-the-counter and prescription uses.	For over-the-counter use.
<b>Configurations</b>	Strip, Cassette, Cup, Dip Card	Cup

## 9. Test Principle

Healgen COC One Step Cocaine Test and Healgen MOP One Step Morphine Test are rapid tests for the qualitative detection of Benzoylecggonine and Morphine in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (monoclonal mouse antibody) coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample.

## 10. Performance Characteristics

### 1. Analytical Performance

#### a. Precision

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled and randomized.

For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

**Cocaine (COC) Strip Format**

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:COC1111001	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111002	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111003	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

**COC Cassette Format**

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:COC1111004	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111005	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111006	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

**COC Dip Card Format**

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:COC1111007	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111008	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111009	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

**COC CUP Format**

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:COC1111010	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111011	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:COC1111012	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

**Morphine (MOP) Strip Format**

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MOP1110001	50-/0+	50-/0+	50-/0+	50-/0+	16-/34+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110002	50-/0+	50-/0+	50-/0+	50-/0+	16-/34+	50+/0-	50+/0-	50+/0-	50+/0-

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MOP1110003	50-/0+	50-/0+	50-/0+	50-/0+	16-/34+	50+/0-	50+/0-	50+/0-	50+/0-

#### MOP Cassette Format

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MOP1110004	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110005	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110006	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

#### MOP Dip Card Format

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MOP1110007	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110008	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110009	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

#### MOP CUP Format

Result Drug	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
Lot:MOP1110010	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110011	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:MOP1110012	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

#### b. Linearity

Not applicable, these are visually read devices.

#### c. Stability

The devices are stable at 4-30°C for 24 months based on the accelerated stability study at 45°C and real time stability determination at both 4 °C and 30°C.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

#### d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% cut-off; -25% cut-off; cut-off; +25% cut-off; +50% cut-off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% cut-off and all negative at and

below -25% cut-off for both Cocaine and Morphine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
<b>One Step Cocaine Test</b>	Benzoylecgonine	300
<b>One Step Morphine Test</b>	Morphine	300

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above cut-off levels. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100 $\mu$ g/mL are summarized in the following tables. There were no differences observed for different formats.

**COC**

4-Acetamidophenol	Fenoprofen	Pentazocine
Acetophenetidin	Furosemide	Pentobarbital
N-Acetylprocainamide	Gentisic acid	Perphenazine
Acetylsalicylic acid	Hemoglobin	Phencyclidine
Aminopyrine	Hydralazine	Phenelzine
Amitriptyline	Hydrochlorothiazide	Phenobarbital
Amobarbital	Hydrocodone	Phentermine
Amoxicillin	Hydrocortisone	L-Phenylephrine
Ampicillin	O-Hydroxyhippuric acid	$\beta$ -Phenylethamine
Ascorbic acid	3-Hydroxytyramine	$\beta$ -Phenylethylamine
D,L-Amphetamine	Ibuprofen	Phenylpropanolamine
L-Amphetamine	Imipramine	Prednisolone
Apomorphine	Iproniazid	Prednisone
Aspartame	(-) Isoproterenol	Procaine
Atropine	Isoxsuprine	Promazine
Benzilic acid	Ketamine	Promethazine
Benzoic acid	Ketoprofen	D,L-Propanolol
Benzphetamine	Labetalol	D-Propoxyphene
Bilirubin	Levorphanol	D-Pseudoephedrine
Brompheniramine	Loperamide	Quinidine
Caffeine	Maprotiline	Quinine
Chloralhydrate	Meprobamate	Ranitidine
Chloramphenicol	Methadone	Salicylic acid

Chlordiazepoxide	Methoxyphenamine	Secobarbital
Chlorothiazide	(+) 3,4-Methylenedioxymphetamine	Serotonin (5-Hydroxytyramine)
(±) Chlorpheniramine	(+)-3,4-Methylenedioxymethamphetamine	Sulfamethazine
Chlorpromazine	Methylphenidate	Sulindac
Chlorquine	Methyprylon	Temazepam
Cholesterol	Morphine-3-β-Dglucuronide	Tetracycline
Clomipramine	Nalorphine	Tetrahydrocortisone,3Acetate
Clonidine	Naloxone	Tetrahydrocortisone3 (5-Dglucuronide)
Codeine	Nalidixic acid	Tetrahydrozoline
Cortisone	Naltrexone	Thebaine
(-) Cotinine	Naproxen	Thiamine
Creatinin	Niacinamide	Thiordiazine
Deoxycorticosterone	Nifedipine	D, L-Thyroxine
Dextromethorphan	Norcodein	Tolbutamine
Diazepam	Norethindrone	Triamterene
Diclofenac	D-Norpropoxyphene	Trifluoperazine
Diflunisal	11-nor-Δ9-THC-9-COOH	Trimethoprim
Digoxin	Noscapine	Trimipramine
Diphenhydramine	D,L-Octopamine	Tryptamine
Doxylamine	Oxalic acid	D, L-Tryptophan
Ecgonine hydrochloride	Oxazepam	Tyramine
Ecgonine methylester	Oxolinic acid	D, L-Tyrosine
(-) Y Ephedrine	Oxycodone	Uric acid
Erythromycin	Oxymetazoline	Verapamil
β-Estradiol	p-Hydroxymethamphetamine	Zomepirac
Estrone-3-sulfate	Papaverine	
Ethyl-p-aminobenzoate	Penicillin-G	

### MOP

Acebutolol	(-) Y Ephedrine	p-Hydroxymethamphetamine
Acetopromazine -d6	Erythromycin	Papaverine
4-Aacetamidophenol	β-Estradiol	Penicillin-G
Acetophenetidin	Estrone-3-sulfate	Pentazocaine
N-Acetylprocainamide	Ethyl-p-aminobenzoate	Pentobarbital
Acetylsalicylic acid	Fenoprofen	Perphenazine

D,L-Amphetamine	Furosemide	Phencyclidine
L-Amphetamine	Gentisic acid	Phenelzine
Aminopyrine	Hemoglobin	Phenobarbital
Amitryptyline	Hydralazine	Phentermine
Amobarbital	Hydrochlorothiazide	$\beta$ -Phenylethylamine
Amoxicillin	Hydrocortisone	L-Phenylephrine
Ampicillin	O-Hydroxyhippuric acid	$\beta$ -Phenylethylamine
Ascorbic acid	3-Hydroxytyramine	Phenylpropanolamine
Apomorphine	Ibuprofen	Prednisolone
Aspartame	Imipramine	Prednisone
Atropine	Iproniazid	Promazine
Benzilic acid	(-) Isoproterenol	Promethazine
Benzoic acid	Isoxsuprine	D,L-Propanolol
Benzoyllecgonine	Ketamine	D-Propoxyphene
Benzphetamine	Ketoprofen	D-Pseudoephedrine
Bilirubin	Labetalol	Quinidine
Brompheniramine	Loperamide	Quinine
Caffeine	Maprotiline	Salicylic acid
Chloramphenicol	Meprobamate	Secobarbital
Chlordiazepoxide	Methoxyphenamine	Serotonin
Chlorothiazide	(+) 3,4-Methylenedioxymethamphetamine	Sulfamethazine
( $\pm$ ) Chlorpheniramine	(+)-3,4-Methylenedioxymethamphetamine	Sulindac
Chlorpromazine	Methadone	Temazepam
Chlorquine	Methylphenidate	Tetracycline
Cholesterol	Methyprylon	Tetrahydrozoline
Clomipramine	Nalorphine	Tetrahydrocortisone,3 Acetate
Clonidine	Nalidixic acid	Tetrahydrocortisone3 (5-Dglucuronide)
Cocaine hydrochloride	Naloxone	Thiamine
Cortisone	Naltrexone	Thioridazine
(-) Cotinine	Naproxen	D,L-Thyroxine
Creatinine	Niacinamide	Tolbutamine
Deoxycorticosterone	Nifedipine	Triamterene
Dextromethorphan	Norcodein	Trifluoperazine
Diazepam	Norethindrone	Trimethoprim
Diclofenac	D-Norpropoxyphene	Trimipramine
Diflunisal	Noscapine	Tryptamine

Digoxin	D,L-Octopamine	D, L-Tyrosine
Diphenhydramine	Oxalic acid	Uric acid
Doxylamine	Oxazepam	Verapamil
Ecgonine hydrochloride	Oxolinic acid	Zomepirac
Ecgonine methylester	Oxymetazoline	

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

COC (Benzoyllecgonine, <b>Cut-off=300 ng/mL</b> )	<b>Result</b> Positive at 300 ng/mL	<b>% Cross-Reactivity</b> 100%
Cocaethylene	Positive at 300 ng/mL	100%
Cocaine HCl	Positive at 300 ng/mL	100%

MOP (Morphine, <b>Cut-off=300 ng/mL</b> )	<b>Result</b> Positive at 300 ng/mL	<b>% Cross-Reactivity</b> 100%
6-Acetylmorphine	Positive at 400 ng/mL	75%
Codeine	Positive at 300 ng/mL	100%
EthylMorphine	Positive at 6240 ng/mL	5%
Heroin	Positive at 600 ng/mL	50%
Hydromorphone	Positive at 3120 ng/mL	10%
Hydrocodone	Positive at 50000 ng/mL	0.6%
Levorphanol	Positive at 1500 ng/mL	20%
Oxycodone	Positive at 30,000 ng/mL	1%
Procaine	Positive at 15,000 ng/mL	2%
Thebaine	Positive at 6240 ng/mL	5%

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three batches of each device for all formats. Results were all positive for samples at and above +25% cut-off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

2. Comparison Studies

The method comparison studies for the One Step Cocaine Test, and the One Step Morphine Test were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

**COC**

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Viewer B	Positive	0	0	0	14	24
	Negative	10	17	13	2	0
Viewer C	Positive	0	0	0	15	24
	Negative	10	17	13	1	0

**Discordant Results of COC Strip**

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	370	303	Negative
Viewer B	370	303	Negative
Viewer B	302	305	Negative
Viewer C	302	305	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Viewer B	Positive	0	0	0	16	24
	Negative	10	17	13	0	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

**Discordant Results of COC Cassette**

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	370	303	Negative
Viewer C	370	303	Negative
Viewer C	302	305	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Viewer B	Positive	0	0	0	16	24
	Negative	10	17	13	0	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

#### Discordant Results of COC Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	370	303	Negative
Viewer C	370	303	Negative
Viewer C	302	305	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Viewer B	Positive	0	0	0	15	24
	Negative	10	17	13	1	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	17	13	2	0

#### Discordant Results of COC Dip Card

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	370	303	Negative
Viewer B	370	303	Negative
Viewer C	370	303	Negative
Viewer C	302	305	Negative

### MOP

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	25
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	1	14	25
	Negative	10	15	14	1	0
Viewer C	Positive	0	0	0	15	25
	Negative	10	15	15	0	0

### Discordant Results of MOP Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	36	307	Negative
Viewer B	60	298	Positive
Viewer B	38	328	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	25
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	14	25

	Negative	10	15	15	1	0
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**Discordant Results of MOP Cassette**

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	36	307	Negative
Viewer A	12	310	Negative
Viewer B	36	307	Negative
Viewer C	36	307	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	25
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	14	25
	Negative	10	15	15	1	0
Viewer C	Positive	0	0	0	13	25
	Negative	10	15	15	2	0

**Discordant Results of MOP Dip Card**

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	36	307	Negative
Viewer A	12	310	Negative
Viewer B	36	307	Negative
Viewer C	36	307	Negative
Viewer C	12	310	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	25

	Negative	10	15	15	1	0
Viewer B	Positive	0	0	0	15	25
	Negative	10	15	15	0	0
Viewer C	Positive	0	0	0	15	25
	Negative	10	15	15	0	0

#### Discordant Results of MOP Cup

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	36	307	Negative

#### Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons testing the cocaine devices and another set of 140 persons testing the morphine devices. A total of 56 females and 84 males tested the Cocaine samples, and 53 females and 87 males tested the Morphine samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

#### Comparison between GC/MS and Lay Person Results (COC Strip)

% of Cutoff	Number of samples	COC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	2	18	90%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

#### Comparison between GC/MS and Lay Person Results (COC Cassette)

% of Cutoff	Number of samples	COC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100%
-75% Cutoff	20	75	0	20	100%

<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	1	19	95%
<b>+25% Cutoff</b>	20	375	19	1	95%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

**Comparison between GC/MS and Lay Person Results (COC DipCard)**

% of Cutoff	Number of samples	COC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100%Cutoff</b>	20	0	0	20	100%
<b>-75%Cutoff</b>	20	75	0	20	100%
<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	1	19	95%
<b>+25% Cutoff</b>	20	375	17	3	85%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

**Comparison between GC/MS and Lay Person Results (COC Cup)**

% of Cutoff	Number of samples	COC Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100%Cutoff</b>	20	0	0	20	100%
<b>-75%Cutoff</b>	20	75	0	20	100%
<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	1	19	95%
<b>+25% Cutoff</b>	20	375	20	0	100%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

**Comparison between GC/MS and Lay Person Results (MOP Strip)**

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100%Cutoff</b>	20	0	0	20	100%
<b>-75%Cutoff</b>	20	75	0	20	100%

<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	2	18	90%
<b>+25% Cutoff</b>	20	375	19	1	95%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

**Comparison between GC/MS and Lay Person Results (MOP Cassette)**

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100%Cutoff</b>	20	0	0	20	100%
<b>-75%Cutoff</b>	20	75	0	20	100%
<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	1	19	95%
<b>+25% Cutoff</b>	20	375	19	1	95%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

**Comparison between GC/MS and Lay Person Results (MOP DipCard)**

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100%Cutoff</b>	20	0	0	20	100%
<b>-75%Cutoff</b>	20	75	0	20	100%
<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	1	19	95%
<b>+25% Cutoff</b>	20	375	17	3	85%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

**Comparison between GC/MS and Lay Person Results (MOP Cup)**

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
<b>-100%Cutoff</b>	20	0	0	20	100%
<b>-75%Cutoff</b>	20	75	0	20	100%
<b>-50% Cutoff</b>	20	150	0	20	100%
<b>-25% Cutoff</b>	20	225	1	19	95%

<b>+25% Cutoff</b>	20	375	20	0	100%
<b>+50% Cutoff</b>	20	450	20	0	100%
<b>+75% Cutoff</b>	20	525	20	0	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

### 3. Clinical Studies

Not applicable.

### 11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity and method comparison of the devices, it's concluded that the Healgen COC One Step Cocaine Test, and Healgen MOP One Step Morphine Test are substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

HEALGEN SCIENTIFIC, LLC  
C/O JOE SHIA  
LSI INTERNATIONAL INC  
504 EAST DIAMOND AVE. SUITE F  
GAIITHERSBURG MD 20877

July 17, 2014

Re: K141647

Trade/Device Name: Healgen COC One Step Cocaine Test (Strip, Cassette, Dip Card, Cup)  
Healgen MOP One Step Morphine Test (Strip, Cassette, Dip Card, Cup)

Regulation Number: 21 CFR 862.3250

Regulation Name: Cocaine and cocaine metabolite test system

Regulatory Class: II

Product Code: DIO, DJG

Dated: June 16, 2014

Received: June 19, 2014

Dear Mr. Joe Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Katherine Serrano -S**

For: Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
**Indications for Use**

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

510(k) Number (if known)  
K141647

Device Name  
Healgen MOP One Step Morphine Test (Strip, Cassette, Dip Card, Cup)  
Healgen COC One Step Cocaine Test (Strip, Cassette, Dip Card, Cup)

**Indications for Use (Describe)**

Healgen COC One Step Cocaine Test is an immunochromatographic assay for the qualitative determination of Benzoylecgonine in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen MOP One Step Morphine Test is an immunochromatographic assay for the qualitative determination of morphine in human urine at a Cut-Off concentration of 300 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

**Type of Use (Select one or both, as applicable)**

Prescription Use (Part 21 CFR 801 Subpart D)  Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Denise Johnson-lyles -S